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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/809,638	FARIS ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7,8,14 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,8,14 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1-4, 7, 8, 14 and 23) in Paper No. 13, received December 26, 2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-4, 7, 8, 14 and 23 are pending.

Claims 15 and 20-22 have been cancelled.

Claims 1-4, 7, 8, 14 and 23 have been amended.

Claims 1-4, 7, 8, 14 and 23 are examined on the merits.

Drawings

3. The drawings are objected to because of reasons cited on attached form PTO 948 completed by draftsman. Correction is required.

Specification

4. The disclosure is objected to because of the following informality: it contains symbols that should be replaced by essential information, such as dates on page 14, line 9; page 50, lines 11 and 13; and page 55, lines 30 and 31. Applicant is requested to review the entire application for such informalities and correction is required.

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 15, line 11; 22, lines 16-20 and 23; page 23, lines 7 and 8; and page 55, line 35. Applicant is required to review the entire application and delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

6. Claims 2-4 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form.

Claim 1 reads on a 125P5C8-related protein comprising the entire polypeptide sequence designated as SEQ ID NO: 2. However, claims 2-4 broadly recite polypeptides that have at least 6-30 contiguous amino acids and the remaining amino acids are undefined. Inherently, SEQ ID NO: 2 contains the 6-30 contiguous amino acids. These claims are not further limiting from claim 1.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-4, 7, 8, 14 and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 8 and 23 are broadly drawn to "[an] isolated 125P5C8-related protein comprising the sequence of SEQ ID NO: 2. Claims 2-4 and 7 are drawn to the said protein, which have at least 6-30 contiguous amino acids of SEQ ID NO: 2 and at least one conservative substitution. The specification has defined 125P5C8-related proteins. The definition provided within the bridging paragraph on pages 9 and 10 encompasses allelic variants, conservative substitution variants, analogs and homologs. The written description in this instant case only sets forth polypeptide, SEQ ID NO:2. The written description is not commensurate in scope with the claims drawn to 125P5C8-related variant and mutated polypeptides embodied by the term "related".

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

With the exception of SEQ ID NO:2, the skilled artisan cannot envision the detailed structure of the encompassed polypeptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

At the time the application was filed Applicants only had possession of SEQ ID NO: 2 and not polypeptides that share less than 100% sequence identity with SEQ ID NO:2. The specification does not evidence the possession of all the possible mutant polypeptides that could be capable exhibiting the alleged wild type 125P5C8 properties

listed on pages 10-13, such as a diagnostic marker. There is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

The full breadth of the claims do not meet the written description provision of 35 U.S.C. 112, first paragraph.

9. Claims 1-4, 7, 8, 14 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement commensurate with the scope of the claimed invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

a. Claims 1-4, 7, 8, 14 and 23 are broadly drawn to a 125P5C8 protein that has at least 6-30 amino acids of SEQ ID NO: 2 and a 125P5C8-related protein that comprises at least one conservative substitution. Specifically, claims 1, 8 and 23 are broadly drawn to "[an] isolated 125P5C8 protein comprising the sequence of SEQ ID NO: 2 and a method of making the said protein, as well as a 125P5C8-related protein. Claims 2-4 and 7 are drawn to the said proteins, which have at least 6-30 contiguous amino acids of SEQ ID NO: 2 and at least one conservative substitution. The specification asserts that the instant specification describes a novel gene, designated as 125P5C8, which is over-expressed in a multiple cancers (prostate, bladder, kidney and colon), see page 2, lines 14 and 15; Table 1 on page 73. The specification while being enabling for the polypeptides having the amino acid sequences of SEQ ID NO: 2, does

not reasonably provide enablement for 125P5C8-related proteins, variants and related proteins that have less 100% sequence identity or with one undefined conservative substitution. The variants encompass allelic variants, conservative substitution variants, analogs and homologs, see bridging paragraph on pages 9 and 10 encompass. The specification does not provide for a method of making 125P5C8 proteins based on fragment polynucleotides and non-coding polynucleotides, 125P5C8-related proteins and non-coding sequence polynucleotides that may bind to SEQ ID NO: 1. The specification is enabled for the polynucleotide sequence, SEQ ID NO: 1, but not for polynucleotides that are variants of the said nucleic acid sequence. Applicants have suggested art-accepted means within the specification by which modifications of 125P5C8 polynucleotides and polypeptides may be produced, see pages 20-22. However, the specification has yet to evidence that 125P5C8-related products manufactured by these modifications possess functions that are commensurate with the functions of the native protein. Nor has the specification provided evidence that the non-coding strands, which may hybridize to a polynucleotide of claim 23 (a)-(f) and contained in an expression vector would encode a 125P5C8 protein. The less than 100% sequence identical amino acids and sequence identical nucleic acids encoding variant proteins may not maintain the activities proposed in the specification. It would seem that specific function(s) would be required to make the encoded protein useful for the applications disclosed in the specification, such as for treating disorders related to prostate, bladder, kidney and colon cancer, see Table 1, page 72 and providing immunogenic or therapeutic compositions and strategies for treating cancers that

express 125P5C8. Since the amino acid sequence of a polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar activity requires a knowledge of and guidance with regard to which amino acid or acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved and detailed knowledge of the ways in which the protein's structure relates to its function. The specification provides essentially no guidance as to which of the infinite possible choices is likely to be successful. The true fact of the state of the art in peptide chemistry is expressed succinctly in the accompanying Lazar article (Molecular and Cellular Biology 8(3): 1247-1252, March 1988). This article presents data that substantiates the fact that the introduction of mutations in an amino acid sequence will yield products with different biological activity from the wild type protein.

From the discussion above, it is clear that the predictability of changes to the amino acid sequence is practically nil as far as biological activities are concerned. The specification fails to provide sufficient guidance to enable one of ordinary skill in the art to make and use the claimed nucleic acids in a manner reasonably correlated with the broad scope of the claims. Without sufficient guidance, the changes which must be made in the nucleic acid sequence, SEQ ID NO: 1 and amino acid residues of SEQ ID NO: 2, which results in less than 100% sequence identity is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue.

b. Claims 1-4, 7, 8, 14 and 23 are broadly drawn to a 125P5C8 protein that has at least 6-30 amino acids of SEQ ID NO: 2 and a 125P5C8-related protein that comprises at least one conservative substitution. The specification asserts that the instant specification describes a novel gene, designated as 125P5C8, which is over-expressed in a multiple cancers (prostate, bladder, kidney and colon), see page 2, lines 14 and 15; Table 1 on page 73. Applicants have not provided any disclosure enabling the use of 125P5C8 and 125P5C8-related proteins for therapeutics or as a diagnostic marker for a specific type of cancer. There is no disclosure designating what variations of SEQ ID NO: 2 could be regarded as enabling one of ordinary skill in the art to use the sequences in any diagnostic method. The experimental design presented in the specification lacks information regarding the applicability of SEQ ID NO: 2 and bound sections of the sequences in diagnostic methods relative to any type of cancer. Given the differing hybridization patterns in Figure 5 it is not reasonable to conclude that 125P5C8, 125P5C8-related and sequences to the nucleic acid encoding the protein would be effective in yielding a discriminate diagnosis between distinct disorders, particularly prostate cancer. Tockman et al. (Cancer Research 52:2711s-2718s, 1992) teach considerations necessary for a suspected cancer biomarker (intermediate end point marker) to have efficacy and success in a clinical application. Although the reference is drawn to biomarkers for early lung cancer detection, the basic principles taught are clearly applicable to other oncogenic disorders. Tockman teaches that prior to the successful application of newly described markers, research must validate the markers against acknowledged disease end points, establish quantitative criteria for

marker presence/absence and confirm marker predictive value in prospective population trials, see abstract. Early stage markers of carcinogenesis have clear biological plausibility as markers of preclinical cancer and **if validated** (emphasis added) can be used for population screening (p. 2713s, column 1). The reference further teaches that once selected, the sensitivity and specificity of the biomarker must be validated to a known (histology/cytology-confirmed) cancer outcome. The essential element of the validation of an early detection marker is the ability to test the marker on clinical material obtained from subjects monitored in advance of clinical cancer and *link* those marker results with subsequent histological confirmation of disease. "This irrefutable link between antecedent marker and subsequent acknowledged disease is the essence of a valid intermediate end point [marker]", see page 2714s, column 1, Biomarker Validation against Acknowledged Disease End Points section. Clearly, prior to the successful application of newly described markers, markers must be validated against acknowledged disease end points and the marker predictive value must be confirmed in prospective population trials, see page 2716s, column 2, Summary section. Tockman reiterates that the predictability of the art in regards to cancer prognosis and the estimation of life expectancies within a population with a disease or disorder is highly speculative and unpredictable.

Based on the analysis and the teachings presented above it would require undue experimentation for the skilled artisan to practice this invention because there is no support in the specification for the enablement of the broadly claimed invention. Therefore, in view of the insufficient guidance in the specification, extensive

experimentation would be required to enable the claims and to practice the invention as claimed.

10. Claim 14 is rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure without complete evidence either that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological materials.

The specification lacks complete deposit information for the deposit of the plasmid designated *Escherichia coli* DH5A 125P5C8PRO in claim 14, lines 9 and 10. It is not clear that the plasmids are known and publicly available or can be reproducibly isolated from nature without undue experimentation. Exact replication of a plasmid is an unpredictable event. It is unclear that one of skill in the art could derive plasmids identical to those claimed. Undue experimentation would be required to screen all of the possible cell lines to obtain the claimed plasmids. Because one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the claimed plasmids, a suitable deposit for patent purposes, evidence of public availability of the claimed plasmids or evidence of the reproducibility without undue experimentation of the claimed plasmids, is required.

If the deposit is made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International

Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. If the deposit is not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability and permanency of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request:

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application:

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. Additional means for completing the record is required. Applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit to aid in obviating the instant rejection.

If deposits are made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the cell line described in the specification as filed is the same as that deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession at the time the application was filed. Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 2, 3, 8 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The recitation "125P5C8-related proteins" in claims 2, 3 and 23 are vague and indefinite. It is not clear what qualities, activities or functions deem a protein as being related to wild-type 125P5C8 proteins.

b. Claim 8 is vague and indefinite in the recitation "an epitope that induces a specific antibody response". It is not clear what type of response Applicants are referencing. Nor is it clear which amino acid residues comprise the epitope capable of inducing the response. The metes and bounds of the claim cannot be determined.

c. Claim 23(g) is vague and indefinite in the recitation " ...wherein a range is understood to specifically disclose all whole unit positions thereof". It is not clear what range and what whole unit positions Applicants are referencing. Accordingly, the metes and bounds cannot be determined.

d. Claim 23(g) is vague and indefinite in the recitation "hybridize under high stringency conditions". While a suggested example of hybridization conditions is provided in the bridging paragraph of pages 7 and 8 of the specification it is absent from the claim. Moreover, this example is not non-limiting and the metes and bounds of the hybridization conditions are not clear.

Claim Rejections - 35 USC § 101

13. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

14. Claims 1-4, 7, 8, 14 and 23 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, credible or substantial asserted utility or a well established utility.

Applicants have asserted several utilities for the claimed isolated polypeptide and polynucleotide, SEQ ID NO: 2 and 1, respectively and variants of said sequences: therapeutics, diagnostic tools and prevention of diseases associated with expression of these sequences, see page 2, lines 14-20; page 10, line 20-page 13, line 5; and page 56, lines 3-32. However, these asserted utilities are neither specific nor substantial. The broadly claimed polynucleotide is based on SEQ ID NO: 1 and allegedly encodes 125P5C8 proteins and related proteins having the sequence designated as SEQ ID NO: 2. According to the specification "125P5C8 exhibits specific properties that are analogous to ....a family of molecules ...are used in well known diagnostic assays that examine conditions associated with dysregulated cell growth such as cancer, in particular prostate cancer..." (see page 10, lines 9-14), as a protein transporter (see Example 12, page 66) and as a mediator of intercellular communications (see Example 13, page 67). However, these observations do not reflect conclusive information that links expression of SEQ ID NO:1 or 125P5C8-related proteins to any specific disease state. The mere fact that 125P5C8 seems to be expressed in malignant prostate, bladder, kidney and colon tissues does not mean that it functions as a diagnostic marker for cancer. Results presented in the figures, particularly Figures 5 and 6A-6C do not support Applicants' asserted use of the claimed methods for detection of any prostate disorders, particularly prostate cancer. There is no disclosure or working

examples that demonstrate the specifically asserted utility and evidences a substantial utility was well established at the time of filing. Applicants have provided information that simply supports the fact that SEQ ID NO: 2 is detectable in many tissues and possibly exclusively in prostate. There is no information supporting the use of the listed sequence or related sequences as a specific tumor marker to be implemented. The specification does not exemplify the use of any of the said sequences in differential expression in normal prostate tissue versus high risk (potentially diseased) prostate tissue/ prostate cancer tissue or their reliability as biomarkers, which may signal a stage of carcinogenesis. Based on the analysis set forth above the specification does not exemplify sufficient findings that constitute a specific, substantial or credible utility.

Claims 1-4, 7, 8, 14 and 23 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial or credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Even if Applicants were to evidence that claims 1-4, 7, 8, 14 and 23 have a patentable utility they would be enable for the full scope of the invention.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

PATENT EXAMINER
ALANA M. HARRIS

Alana M. Harris, Ph.D.
March 6, 2003